Project Summary

The overall aim of the CORAL4HEALTH project was to prepare its sole beneficiary, Zoan BioMed, to commercialise the next generation graft bone substitutes, drawn from a sustainable, ethical and high-quality source of biomaterial (cultured coral). The major challenge which the project aims had to overcome, was the utilization of an important marine resource, the ability to supply at scale without having an environmental impact or affecting the sustainability of that natural product which is heavily protected in the wild. Through the CORAL4HEALTH project, we believe we are the only company in Europe (and indeed in the world) innovating such a design of a medical device in the world of orthopedics with a commercially viable solution. The project has also made significant progress in bringing Zoan to industrial scale, building on past work, as well as putting in place the regulatory and quality approvals needed to launch its product onto the market.

The key outcomes and deliverables from the Coral4Health Project were as follows:

- validated our ability to culture several species of coral in controlled conditions to a standard required for biomedical applications.

- developed and refined new practices to preserve the bone graft qualities of the coral scaffolds, with emphasis on interconnected porosity, integral strength, and mineral composition. These practices include harvest methods, the devitalisation process, optional bleaching and rinsing processes along with drying methodologies.

- developed Standard Operating Procedures (SOPs) to ensure the repeatable, validated operation of the processes to optimise the safety and efficacy of the coral post-harvest and ensure the standards can be translated into an ISO 13485 framework (International Organization for Standardization, Quality Management System for Medical Devices 13485)

- achieved the ISO 13485 Quality Management System for Medical Device. This was a fundamental step ahead of market approval and registration of our Zoan G03 product in the US and Europe

- demonstrated our ability to consistently produce coral material that will be suitable for implant to the human body through the design and adherence of our processes to ISO 13485 standards

- carried out gamma irradiation in sterilising the product itself, the vial which contains it and the packaging (Pouch/carton)

- submitted an application for FDA approval of our product G03.

- carried out an assessment of the market opportunity within Orthopaedics, including current market players, competitive products, and areas of potential collaboration

- carried out multiple other market assessments on potential uses for our developed material – including 3D Printing market (as represented by our partnership with BICO / Cellink). Assessed the role our facilities could play as a future product testing site for Cosmetics industry assessing product impact in the Oceans. The latter opportunity in Cosmetics is at an early stage and under NDA but could offer a new business opportunity for us to utilise our management team's skill set and experience in coral culturing

- detailed financial projections have also been forecast along with the development of a sustainability plan

- developed and initiated a market entry plan to launch product ZoanG03

- explored opportunities in complimentary high value sectors such as 3D additive manufacturing, Dentistry and Veterinary care. The 3D additive manufacturing is a key part of our work with BICO / Cellink.

- Zoan were finalists in the EIT Catapult Programme. A unique competition and training programme that showcases biotech, MedTech and digital health start-ups to leading experts and investors across Europe. This one-of-a-kind, rigorous and rewarding competition spotlights start-ups that offer best value to users and customers. Throughout the process, Zoan received intensive training and visibility through pan-European exposure to investors.. https://eithealth.eu/programmes/catapult/

- Designed specifications for a second-generation product, a putty, for bone healing and repair

- The Gen 2 product has been designed and we have a prototype of the device built and shared with Surgeons

- Significantly developed the site of production, allowing set up for future scale